

1024-50

Recanalized Chronic Total Occlusions Covered by Sirolimus-Eluting Stents

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Background: Chronic total coronary occlusions leading to residual myocardial ischemia may be recanalized and scaffolded by stents. The initial and long-term efficacy of this treatment with bare stents is well known. A high restenosis rate (20-30%) remains the main limitation. At present, there is little information on the use of Rapamycin-eluting stents (RES) to treat chronic total occlusions. **Methods:** Since May/02 we have prospectively analyzed the initial and late findings observed in a consecutive series of 86 patients (pts) with angina pectoris due to chronic total coronary occlusion in whom we attempted recanalization and subsequent covering by RES. The mean age was 60±10 years; 65 (76%) were male. The underlying clinical condition was stable angina in 15 pts and unstable angina in 71 pts; 34 had had a previous myocardial infarction. The estimated occlusion time in 49 pts was 9±21 months; however, the overall duration of symptoms was 2.5±3 years. At cardiac catheterization, left ventricular end-diastolic pressure was 21±8 mmHg and the ejection fraction 58±13%. One patient had 2 occluded arteries. Recanalization was attempted with the safer-cross radiofrequency wire in 20 pts because of unfavourable anatomy or too old occlusion; in the remaining 66, recanalization was attempted with regular guide-wires. Once recanalization had been achieved (86%) balloon dilatation and subsequent scaffolding with RES was performed. **Results:** Primary success was obtained in 74 pts. In the remaining 12 pts (14%) we failed to cross the occlusion. Two pts (2.3%) had a cardiac tamponade that was resolved by percutaneous drainage in the laboratory. All recanalized pts became symptoms free. After a mean clinical follow-up time of 6±3 months, 5 pts (6%) needed new target lesion revascularization. Thirty-nine pts underwent 6-month follow-up angiographic and intracoronary ultrasound (IVUS) re-evaluation. The mean neointimal area, as derived by IVUS, was 1.1±1.8 mm². Restenosis rate was 13%. **Conclusion:** The use of drug-eluting stents to cover recanalized chronic total occlusions is safe and seems to significantly reduce the need for further target vessel revascularization.

1024-51

Evaluation of Sirolimus-Eluting Stents for the Treatment of Bifurcation Lesions: A Real World Study

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Background: Although bare metal stents have been a useful therapeutic modality for the treatment of bifurcation lesions using a "provisional T stenting strategy", they have not eliminated the problem of restenosis. Sirolimus-eluting stents have been shown to markedly decrease restenosis in selected lesions.

Methods: We evaluated from our prospective database on bifurcation lesions the outcome of patients who underwent treatment with sirolimus-eluting stents.

Results: Between May 2002 and July 2003, a total of 140 patients underwent coronary stenting for the treatment of bifurcation lesions and of these 48 patients (49 lesions) were treated with a Cypher stent. They were 64±8 years, 73% male, 48% diabetes mellitus, and 30% had unstable angina. Lesions were true bifurcation lesions in 49% of cases. Bifurcations involved mainly LAD/ Diagonal (63%). The reference diameter of the main and side branch was 3.0±0.4 mm and 2.0±0.2 mm respectively. Provisional T-stenting of the side branch was used in 86% of cases (side branch was stented in 11% of cases), systematic T stenting in 9% and V stenting in 5 % of cases. In the provisional T-stenting group, all patients had final kissing balloon inflation after opening the stent strut. Device success was obtained in all cases. Angiographic success was 100% and 97.6% for the main and the side branch respectively. In-hospital period was uneventful except for asymptomatic CPK elevation in one patient. Of the 28 patients who completed 6 month follow-up, there were no case of stent thrombosis, death or MI. Two patients had angiographic restenosis, first was focal in-stent restenosis of the main branch and the second, ostial restenosis of the unstented side branch.

Conclusion: Implantation of the sirolimus-eluting stent at coronary bifurcations mainly using a strategy of provisional T stenting results in low clinical event rates. These preliminary results appear very promising. Six-month results of the total cohort will be presented at the meeting.

1024-52

The Crushing Technique for Bifurcation Lesions: Immediate and Mid-Term Clinical Outcome

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Background: different modalities of stenting have been proposed for bifurcational lesions requiring one or two stents positioned with different techniques.

Methods: we report the immediate and 6-months clinical outcome of a new stenting technique employed in the first 91 consecutive bifurcational lesions from 86 patients using drug eluting stents (Sirolimus, n=73, Taxol, n=13). This new mode of bifurcational stenting, reproduces the same steps of the modified T-stenting with the only difference being the protrusion of the side branch stent into the main vessels for 4-5 mm from the carina. The aim of this technique is to ensure that the ostium of the side branch is circumferentially covered with stent struts with the additional advantage of a higher dosage of eluted drug near the bifurcational site.

Results: angiographic success was reached in all the lesions (final kissing balloon inflation in 63% of the lesions). Bifurcational lesions were located as follows: LAD-diagonal branch 48%, LCX-OM 27%, RCA 11%, LM 11%. Procedural success was obtained in 82 (95.3%) patients. During hospital stay, no patient died; 3 (4.7%) patients had myocardial

infarction. All the patients have been discharged with double antiplatelet therapy for at least 6 months. No other major adverse cardiac events were observed during the first month of follow-up. After 6-months clinical follow-up no patients died, 2 (2.3%) patients had myocardial infarction. Target lesion revascularizations (TVR) were performed in 8/42 (19%) patients (on the main branch in 1 case, on the side branch in 7 cases). A lower, even though not statistically different, incidence of TVR was observed in the lesions where a final kissing balloon inflation was performed (8% with kissing vs 20% without kissing, p=0.45).

Conclusions: treatment of bifurcation lesions using the "crushing" stent technique is feasible with acceptable rate of procedural complications. Need of repeat revascularization have been found to be low on the main branch, but relatively high on the side branch. Final kissing balloon inflation can be a potential mean to improve the mid term outcome but need to be confirmed in further evaluations.

1024-53

Drug-Eluting Stents for Coronary Bifurcations: Bench-Top Insights Into the "Crush" Technique

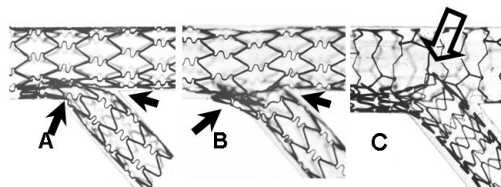
John A. Ormiston, Erin Currie, Mark Wl Webster, Patrick Kay, Peter N. Ruygrok, James T. Stewart, Monique J. Panther, Mercy Angiography, Auckland, New Zealand

Background: Compared with bare metal stents, sirolimus-eluting stents appear to reduce restenosis after bifurcation stenting. The "crush" technique is proposed to further reduce restenosis by improving stent and drug application to the side-branch ostium.

Aims: To investigate the "crush" technique for different drug-eluting platforms, to identify pitfalls and clarify the best implantation strategies.

Methods and Results: Each stage of the "crush" technique was photographed in a bifurcation phantom for 3 stent designs (BxVelocity, Express II, and Driver). Simultaneous side-branch and main vessel post-dilatation ("kissing" balloons) with appropriately sized balloons, fully expanded the stent in the side-branch ostium (A to B in figure), widened the gaps between stent struts covering the side-branch, and prevented or corrected main vessel stent distortion which occurred if the main vessel was post-dilated with an under-sized main vessel balloon (C).

Conclusions: Appropriate side-branch and main vessel post-dilatation is needed to expand the stent at the ostium fully, to widen gaps between stent struts overlying the side-branch (facilitating subsequent access), and to prevent stent distortion. These principles applied to all bifurcation stent strategies and stent designs tested.



1024-54

Low Repeat Revascularization Rates Following Drug-Eluting Stent Implantation in De Novo Bifurcation Lesions

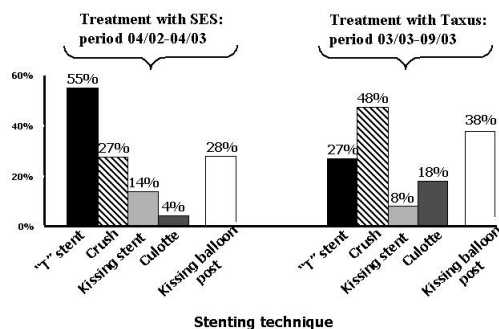
Angela Hoye, Pedro A. Lemos, Kengo Tanabe, Chourmouzios Arampatzis, Francesco Saia, Jiro Aoki, Muzaffer Degertekin, Andrew T L Ong, Carlos van Mieghem, Sjoerd H. Hofma, Georgios Sianos, Pieter C. Smits, Willem van der Giessen, Eugene McFadden, Pim de Feyter, Patrick W. Serruys, Thoraxcenter, Rotterdam, The Netherlands

Background: Bifurcation lesions demonstrate high restenosis when treated with conventional stents. We evaluated both the sirolimus-eluting (SES) and paclitaxel-eluting stent (PES) in this high risk population.

Methods: Since April 2002, the default strategy at our institution was to use drug-eluting stents in all patients. In the 2nd quarter of 2003, we switched from SES to PES for all procedures. The current study evaluated 199 consecutive patients treated for de novo bifurcation stenoses with either SES (n=127) or PES (n=72) implantation into both main vessel and side branch. All were followed-up for clinical events, with additional angiography in those enrolled in the first 6 months.

Results: Presentation: stable angina 60%, acute myocardial infarction 12%. There were 5 subacute thromboses (2.5%), 4 in patients initially treated for AMI. A total of 228 lesions were treated. Target lesion revascularization rate was 7%, and target vessel revascularization (TVR) 9%. Follow-up angiography (in 70% of those eligible), revealed binary restenosis of 9% in the main vessel and 14% in the side branch. 5 of the 6 side branch restenoses were ostial and followed T-stenting. The stenting technique used is depicted in the figure. Further follow-up data of both periods will be available at the ACC.

Conclusions: Both SES and PESs used for bifurcation lesions, demonstrate a low rate of TVR. Ensuring complete lesion coverage with drug-eluting stents may further reduce restenosis particularly at the ostium of the side branch.



POSTER SESSION

1025

Percutaneous Interventions: Pharmacologic and Biologic Adjuncts

Sunday, March 07, 2004, Noon-2:00 p.m.
Morial Convention Center, Hall G
Presentation Hour: 1:00 p.m.-2:00 p.m.

1025-41

Insulin Sensitizers Are Associated With Improved Outcomes in Diabetic Patients Undergoing Brachytherapy

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BACKGROUND: Diabetics have worse baseline disease and higher restenosis rates than non-diabetics. Insulin sensitizers may decrease cardiovascular events in diabetics. Our goal was to determine the effect of insulin sensitizers on clinical events of diabetics undergoing brachytherapy for in-stent restenosis.

METHODS: Diabetics receiving brachytherapy in SCRIPPS I, II, III, and IV at Scripps Clinic were divided into two groups; insulin sensitizers (biguanides or thiazolidinediones, n=50), and non-sensitizers (insulin, sulfonylureas or diet, n=67). Clinical events were defined as target vessel revascularization (TVR), MI (STEMI and NSTEMI), non-TVR, and death.

RESULTS: By 12 months a significant reduction in the composite endpoint was observed in the insulin sensitizer group with a significant decrease in the individual endpoint of Death. Treatment with an insulin sensitizer was the strongest predictor of clinical events (OR=3.47, p=0.0035). This effect was independent of adjunctive medical therapy for coronary artery disease. Patients treated with insulin alone had equivalent outcomes compared to patients treated with sulfonylureas or sulfonylureas with insulin (p>0.05 for all comparisons).

CONCLUSIONS: Insulin sensitizers improve clinical outcomes and convey a mortality benefit in diabetics undergoing brachytherapy for in-stent restenosis. The increased events in the non-sensitizer group is not driven by patients receiving insulin therapy.

	Sensitizers N=50	Non-Sensitizer Therapy N=67	P Value
6-Month Combined Event Rate (%)	27.3%	31.9%	0.72
Death	0	7%	0.13
MI	6%	9%	0.81
TVR	18%	18%	0.33
Non-TVR	15%	10%	0.33
12 Month Combined Event Rate (%)	37%	57.4%	0.041
Death	0	10%	0.049
MI	6%	12%	0.44
TVR	30%	30%	0.61
Non-TVR	10%	15%	0.61

1025-42

Abciximab Administration for the Prevention of Angiographic Restenosis in Small Coronary Arteries: Results From the Randomized ISAR-SMART-2 Trial

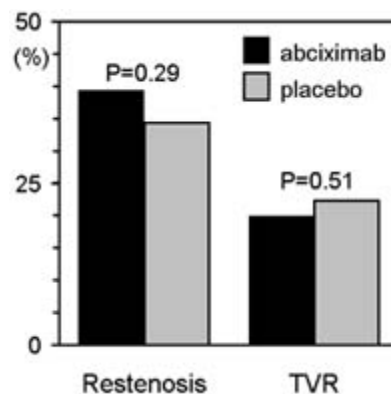
Jörg Hausleiter, Adnan Kastrati, Julinda Mehilli, Helmut Schühlen, Sonja Siebert, Franz Dotzer, Josef Dirschinger, Albert Schömig, Deutsches Herzzentrum München, Munich, Germany, 1.Medizinische Klinik, Klinikum rechts der Isar, Munich, Germany

On the basis of non-dedicated studies it is believed that abciximab reduces the risk of restenosis after percutaneous coronary interventions. In the current multi-center trial, patients with symptomatic coronary artery disease and lesions in small coronary arteries (vessel size < 2.8mm) were randomized to receive stenting (phosphorylcholine-coated stent) or PTCA as well as abciximab or placebo by a 2x2 factorial design. The objective of the pharmacological aspect of the ISAR-SMART-2 trial was to assess whether abciximab administration is associated with a reduction in angiographic restenosis in small coronary arteries.

Methods: From July 2000 through May 2002, a total of 502 patients were randomly assigned to abciximab administration (251 pts) or placebo (251 pts). The primary end-point of the study was the incidence of angiographic restenosis ($\geq 50\%$ diameter stenosis) at repeat angiography (available in 82% of patients). All patients received a loading dose of 600mg clopidogrel at least 2 hours before the intervention.

Results: The incidence of major adverse cardiac events did not differ at 30 days after intervention. The restenosis rate and the rate of target vessel revascularization at 1 year are shown in the Figure.

Conclusion: These results show that abciximab administration on top of an high-dose clopidogrel loading does not provide protection against restenosis after percutaneous coronary interventions in small coronary arteries.



1025-43

Bivalirudin Confers Antiplatelet Effects in Patients Undergoing Percutaneous Coronary Intervention

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Background: Thrombin activity is paramount in the formation of platelet-mediated acute thrombosis precipitated by atherosclerotic plaque rupture or endothelium disruption resulting from mechanical intervention. The objective of this study was to investigate and compare the effects of a bivalent direct thrombin inhibitor, bivalirudin, with unfractionated heparin (UFH) on platelet function in the setting of percutaneous coronary intervention (PCI).

Methods: Patients (mean age 61.7 ± 11.1) were administered an intravenous 0.75 mg/kg bolus followed by a 1.75 mg/kg/hr infusion of bivalirudin (n=12) or an intravenous 40-50 U/kg bolus of UFH (n=15) during PCI. No patient received a pre-loading dose of clopidogrel. Blood samples were collected from patients at baseline and 5 minutes after drug administration from the femoral artery access sheath. To determine platelet function (by assessing platelet surface coverage), the cone and platelet analyzer assay was performed on all samples at a high shear rate (1875 s^{-1}). Computerized planimetry measurements were performed, and 4 to 16 images per timepoint were quantified for platelet surface coverage (PSC) in a blinded fashion.

Results: Direct thrombin inhibition by bivalirudin resulted in a marked $34 \pm 6\%$ reduction in PSC as compared to baseline values ($p < 0.001$). On the other hand, UFH demonstrated a remarkable $29 \pm 8\%$ increase in PSC as compared to baseline values ($p < 0.05$). No clinical sequelae were experienced by any patient.

Conclusion: Our data suggests that direct thrombin inhibition by bivalirudin administration during PCI confers a profound anti-platelet effect as compared to UFH. Interestingly, UFH administration leads to significant platelet activation and aggregation during PCI.